

APR 29 2002

K020911

MID Labs Autonomous Vit Enhancer  
Premarket Notification

510(k) Summary of Safety and Effectiveness

Contact Person: Linda Upton  
MID Labs, Inc.  
14477 Catalina Street  
San Leandro, CA 94577  
(510) 357-3952

Date Prepared:

Trade Name: Autonomous Vit Enhancer  
Common Name: Vitrectomy Device  
Classification Name: Vitreous Aspiration & Cutting Instrument  
(86 HQE, 21CFR 886.4150)

Device Description/ Intended Use: Autonomous Vit Enhancer is a stand alone console box with accessories, designed to be used in conjunction with a standard vitrectomy machine for vitreous cutting.

Predicate Device: MID Labs Vit Enhancer™, MID Labs SupraVit® Vitreoretinal Surgical System

Predicate Device Comparison Table

Device Description	Autonomous Vit Enhancer	Vit Enhancer	SupraVit
510(k) Number	current	K992943	K932669
Intended Use	vitreous cutting	vitreous cutting	Posterior segment ophthalmic surgery, including vitreous cutting
Vitreous Cutter Type	guillotine	guillotine	Guillotine
User interface	Frequency setting and display on front panel	Frequency setting and display on front panel	Frequency setting and display on front panel
Energy source	Internal input pneumatic energy	External input pneumatic energy	Internal or external input pneumatic energy
Internal pressure control	Pressure regulator to control the captured pneumatic energy	Pressure regulator to control the captured pneumatic energy	Pressure regulator to control the captured pneumatic energy
Output valve type	Solenoid valve	Solenoid valve	Solenoid valve
Output frequency control	Electronic signal at user settable frequencies	Electronic signal at user settable frequencies	Electronic signal at user settable frequencies



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 29 2002

Medical Instrument Development  
Laboratories, Inc.  
c/o Linda M. Upton  
14477 Catalina St.  
San Leandro, CA 94577

Re: K020911

Trade/Device Name: Autonomous Vit Enhancer  
Regulation Number: 21 CFR 886.4150  
Regulation Name: Vitreous Aspiration & Cutting Instrument  
Regulatory Class: Class II  
Product Code: HQE  
Dated: March 15, 2002  
Received: March 20, 2002

Dear Ms. Upton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink that reads "A. Ralph Rosenthal". The signature is written in a cursive, flowing style.

A. Ralph Rosenthal, M.D.  
Director  
Division of Ophthalmic and Ear,  
Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

510(k) Number (if known): K020911

Device Name: Autonomous Vit Enhancer (AVE)

Indications For Use:

The AVE is used in conjunction with ophthalmic surgical equipment (typically phacoemulsification or vitreoretinal surgical equipment) to remove vitreous and intraocular tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

(Division Sign-Off)  
Division of Ophthalmic Ear,  
Nose and Throat Devices

510(k) Number K020911

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)